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10/586,630	07/19/2006	Yoshikazu Konno	294006US0PCT	6098
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ART UNIT	PAPER NUMBER			
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/586,630	Applicant(s) KONNO ET AL.
	Examiner TANIA ASHBY	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 July 2006.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1448)
Paper No(s)/Mail Date 19 July 2006, 12 September 2006

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Status of the Claims

Instant claims 1-8 are currently pending and are the subject of this office action.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The earliest effective date afforded to the instant claims is January 20, 2004.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on July 19, 2006 and September 12, 2006 were noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered all references and/or information within the information disclosure statements that have been provided in English.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 provides for the use of the cosmetic according to any one of claims 1 to 7, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite

where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruskin (U.S. Pat. 2,539,483, issued January 30, 1951) and Sugai et al. (U.S. Pat. 6,063,366, issued May 16, 2000).

The Ruskin reference is drawn to preparations of urea ascorbate (column 1, lines 14-15) that have notably improved solubility and stability properties combined with metal salts, including sodium (column 2, lines 23-26). Such preparations are taught as being incorporated into ointments or cosmetics (column 6, lines 63-68).

The Ruskin reference, while teaching the combination of L-ascorbic acid with urea and arginine and the inclusion of a metal salt, does not teach the specific use of L-ascorbic acid 2-phosphate sodium salt and does not teach the inclusion of a salt which produces an alkali metal ion in water.

The Sugai et al. reference teaches the explicit use of L-ascorbic acid 2-phosphate sodium salt as an anti-melanogenic agent in a cosmetic composition (column 4, lines 47 and 55-57).

Regarding claim 1, Example 5 of the Ruskin reference teaches the combination of ascorbic acid with urea and arginine (see lines 3-14 of column 5). The Sugai et al. teaches the explicit use of L-ascorbic acid 2-phosphate sodium salt as an anti-melanogenic agent in a cosmetic composition (column 4, lines 47 and 55-57). Neither reference teaches the claimed mass ratio of components (A):(B). However, the Ruskin

reference does teach the amount of urea and arginine (i.e. component B) as 6 grams urea and 17.4 grams arginine (see example 5) and furthermore teaches that the ratio of urea may be varied (see example 3, 1.2 g urea used) while still achieving a result of increased stability. Furthermore, the Sugai et al. reference teaches that the weight percent of the anti-melanogenic agent [i.e., the L-ascorbic acid 2-phosphate, component (A)] may vary from 0.01% - 10% (column 5, line 40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to look at the guidance provided by Ruskin and Sugai et al. and manipulate the concentration of the components in the formulation. One would have been motivated to do so during the routine optimization process depending on the desired properties of the final formulation. Furthermore, ranges and/or specific percentages arising from routine optimization are generally not inventive absent a showing of unexpected results from the claimed range and/or percentage.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to be motivated to combine the teachings of the Ruskin reference with the L-ascorbic acid 2-phosphate sodium salt taught by the Sugai et al. reference because the Sugai et al. reference suggests that anti-melanogenic agents such as L-ascorbic acid 2-phosphate sodium salt can improve spots, freckles and a dark complexion caused by melanin pigment. This is especially advantageous to the instant invention because the instant invention is drawn to a cosmetic composition and users of such products desire an even skin tone. In addition, derivatives of L-ascorbic acid are also known to attribute the advantage of increased stability (as opposed to L-

ascorbic acid alone) of the composition to oxygen or heat (see column 1, lines 28-31 of the Ohmori et al. reference). This is advantageous to the instant invention as it will consequently increase the shelf life of the product.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruskin (U.S. Pat. 2,539,483, issued January 30, 1951) and Sugai et al. (U.S. Pat. 6,063,366, issued May 16, 2000), as applied to claim 1 above, and further in view of Ohmori et al. (U.S. Pat. 6,388,098, published May 14, 2002).

The Ruskin reference is drawn to preparations of urea ascorbate (column 1, lines 14-15) that have notably improved solubility and stability properties combined with metal salts, including sodium (column 2, lines 23-26). Such preparations are taught as being incorporated into ointments or cosmetics (column 6, lines 63-68).

The Ruskin reference, while teaching the combination of L-ascorbic acid with urea and arginine and the inclusion of a metal salt, does not teach the specific use of L-ascorbic acid 2-phosphate sodium salt and does not teach the inclusion of a salt which produces an alkali metal ion in water.

The Sugai et al. reference teaches the explicit use of L-ascorbic acid 2-phosphate sodium salt as an anti-melanogenic agent in a cosmetic composition (column 4, lines 47 and 55-57).

The Ohmori et al. reference is drawn to a process for preparing an ascorbic acid 2-monophosphate salt in the presence of a magnesium ion (abstract).

Regarding claim 2, the Ohmori et al. reference teaches the incorporation of component (C), namely a magnesium compound such as magnesium chloride that is

capable of supplying a magnesium (i.e. alkali metal) ion in water (see claims 3 and 5 of the reference). Neither reference teaches the claimed mass ratio of components (A):(C). However, the Sugai et al. reference teaches that the weight percent of the anti-melanogenic agent [i.e., the L-ascorbic acid 2-phosphate, component (A)] may vary from 0.01% - 10% (column 5, line 40) and the Ohmori et al. reference teaches that the amount of the magnesium ion may vary from 1.1 to 2.0 mol (see column 5, lines 40-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to look to the guidance provided by Sugai et al. and Ohmori et al. and manipulate the concentration of (A):(C) in the formulation. One would have been motivated to do so during the routine optimization process depending on the desired properties of the final formulation. Furthermore, ranges and/or specific percentages arising from routine optimization are generally not inventive absent a showing of unexpected results from the claimed range and/or percentage.

Regarding claim 3, the Sugai et al. reference teaches the sodium L-ascorbic acid phosphate (i.e., the anti-melanogenic agent) in an amount of 0.01-10% (column 5, lines 38-40). Where the prior art ranges overlap or encompass the claimed ranges, a *prima facie* case of obviousness exists (MPEP 2144.05).

Regarding claim 4, the Ruskin reference teaches a combination of arginine and urea (see example 5 of the reference).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to be motivated to combine the teachings of the Ruskin reference and the Sugai et al. reference with the magnesium salt of the Ohmori et al.

reference because the Ohmori et al. reference suggests that the magnesium ion will prevent the decomposition of L-ascorbic acid 2-monophosphate to L-ascorbic acid. This property is advantageous to the instant invention because L-ascorbic acid is less stable than the phosphate counterpart and if formed, would be subject to decomposition and could attribute negative properties such as odor to the product.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruskin (U.S. Pat. 2,539,483, issued January 30, 1951), Sugai et al. (U.S. Pat. 6,063,366) and Ohmori et al. (U.S. Pat. 6,388,098, published May 14, 2002), as applied to claims 1-4 above, and further in view of Candau et al. (U.S. Pat. 5,629,004, issued May 13, 1997).

The Ruskin reference is drawn to preparations of urea ascorbate (column 1, lines 14-15) that have notably improved solubility and stability properties combined with metal salts, including sodium (column 2, lines 23-26). Such preparations are taught as being incorporated into ointments or cosmetics (column 6, lines 63-68).

The Sugai et al. reference teaches the explicit use of L-ascorbic acid 2-phosphate sodium salt as an anti-melanogenic agent in a cosmetic composition (column 4, lines 47 and 55-57).

The Ohmori et al. reference is drawn to a process for preparing an ascorbic acid 2-monophosphate salt in the presence of a magnesium ion (abstract).

The above references do not teach the specific use of potassium chloride or sodium chloride salt as component (C).

The Candau et al. reference is drawn to an emulsion containing stabilized ascorbic acid.

Regarding claim 5, the incorporation of either sodium or potassium chloride is taught by the Candau et al. reference in column 4, lines 52-55.

Regarding claim 6, the Ruskin reference teaches the use of the composition in cosmetics in column 6, lines 63-68. Example 5 of the Ruskin reference further teaches an aqueous cosmetic.

Regarding claim 7, the Ohmori et al. reference teaches the preparation of an ascorbic acid phosphate salt at a pH of 7 or more (abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art to be motivated to combine the teachings of the Sugai et al., Ohmori et al., and Ruskin references with the sodium or potassium chloride taught by the Candau et al. reference because the Candau et al. reference suggests that the use of an electrolyte such as sodium or potassium chloride will further stabilize the product (column 4, lines 52-55). Increased stability is advantageous to the instant invention in that it will increase the shelf life of the product.

In regards to the pH of the preparation, it would have been *prima facie* obvious to one having ordinary skill within the art to be motivated to adjust the pH to at least 7 because the Ohmori et al. reference suggests that a pH of less than 7 will ultimately result in the decomposition of the ascorbic acid phosphate into ascorbic acid (column 5, lines 60-66). This is disadvantageous to the instant invention because ascorbic acid is

known in the art to be unstable (see column 1, lines 28-30 of the Ohmori et al. reference).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yu et al., U.S. 2004/0033963, published February 19, 2004. The Yu et al. reference is drawn to a cosmetic composition comprising urea.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TANIA ASHBY whose telephone number is (571)270-1348. The examiner can normally be reached on Monday through Friday, 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tania Ashby/
Patent Examiner, Art Unit 1611